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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,240	NAGAOKA ET AL.	
	Examiner	Art Unit	
	P. Kathryn Wright	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 December 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-8 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 01 April 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed December 26, 2007 in which claims 1-8 were amended and claims 9-13 were canceled. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated June 26, 2007 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments. New grounds for rejection, necessitated by the amendments are discussed. Note claim 1 now recites previously unclaimed limitations, e.g., reagent cartridge protecting sheet and testing cartridge protecting sheet.

Claims 1-8 are under prosecution.

Drawings

2. The drawings are again objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "housing part" (claim 1 and 2), "sample channel" (claim 1), and "reaction region" claim 1, must be shown or the features canceled from the claims. Similarly, the "first storing portion" and "second storing portion" in claim 3 must be shown or the features canceled from the claims. No new matter should be entered.

Applicant states at page 2, last paragraph, of the Reply, filed December 26, 2008, "the housing part can include, for example, a holding disk 12", the "sample

channels are shown in the drawings, including, e.g., serum capillary 316 in Figure 12", and the "reaction region is shown as, e.g., reaction chamber 420 in Figure 15". In addition Applicant points to "a plurality of reagent storing parts" are shown as, e.g., element 220, 240, 250, 260, and 270 in the drawings, and the "first storing portion may be represented as, e.g., 220 and a second storing part as, e.g., part 230."

The Examiner asserts this correlation between parts in the Reply is not sufficient. The rules of the PTO require that application claims must conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description (this includes the DETAILED DESCRIPTION OF THE INVENTION) so that the meaning of the terms in the claims may be ascertainable by reference to the description. 37 CFR 1.75(d)(1).

Thus, Applicant should either amend the claims elements so that they correspond to the specification, or amend the DETAILED DESCRIPTION OF THE INVENTION portion of the specification to include the claim language ("housing part", "sample channel", "reaction region", "first storing portion" and "second storing portion") with the corresponding reference numbers while being careful that two separate elements do not use the same reference number or vice-versa. This allows one to ascertain the meaning of the terms in the claims may be ascertainable by reference to the description and not the prosecution history.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2 and 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The analyzer is not a positively recited element of the invention. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Furthermore, the recitation of the analyzer of claim 2 is confusing and indefinite. It is not clear how the "to which a sample is injected and in which the reagent for reacting with the sample is different than the structure".

Claim 7 recites “wherein a plurality of said reagent cartridges are provided, and a first of said of the reagent cartridges is disposed facing toward a first region of the testing cartridge and a second of said plurality of reagent cartridges is disposed facing toward a second region of the testing cartridge”. No first region or second region of the testing cartridge has been established, thus the Examiner is unable to determine the metes and bounds of the claim. Same deficiency was found in claim 8.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Takayama et al. (US Patent Pub. No. 2006/0166357), hereinafter “Takayama”.

Takayama teaches housing part 80 for housing a structure (formed by components 60, 50, 40, 70). Note that the housing part of claim 1 can reads on any surface .

The Takayama system includes a mechanism for detecting (cell detection) see paragraph [0042]. With respect to claim 2, since the detector is not shown within the assembly of structure defined by the modular components 60, 50, 40, it is disposed outside the structure. The system of Takayama also includes a separate reagent cartridge 50, 60 having a plurality of reagent storing parts (reservoirs 53-59) for storing

the reagent (e.g., organic polar fluid) and a reagent outlet (reads on lower portion of reservoirs).

Takayama also teaches a testing cartridge (microfluidic device 40) having a reagent inlet (41 or 42) to which the reagent outlet of the reagent cartridge can be connected when the structure is assembled. The microfluidic device 40 includes a reagent channel (43 or 44) through which the reagent flows, a sample channel (43 or 44) through which sample flows, and a reaction region 45. Note that the reaction region does not contain any structure that distinguishes it from the channel 45. Channel 45 is in communication with the reagent channel and the sample channel (see Fig. 5).

The Takayama system includes a reagent cartridge protecting sheet 52 (reads on elastomeric film) covering the reagent outlet of the reagent cartridge and a testing cartridge protecting sheet covering reagent inlet 41, 42 (reads on additional elastomeric layer on top of the microfluidic device discloses in paragraph [0039]).

The Takayama reference is silent as to the process of forming the structure by removing the reagent cartridge protecting sheet and the testing cartridge protecting sheet and attaching the reagent cartridge and the testing cartridge so that the reagent outlet is fitted to the reagent inlet recited in claim 1. However, this limitation is considered by the Examiner as product-by-process limitation. Thus, this limitation does not impart distinctive structural characteristics to the final product since the claimed product appears to be the same or similar to that of the prior art, although produced by a different process. As set forth above, the claimed and prior art products are at least

substantially identical in structure. Thus, a *prima facie* case of either anticipation or obviousness has been established.

A product-by-process claim is one in which a product is defined at least in part in terms of the method or process by which it is made. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). See MPEP 2113 [R-1].

The Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to Applicant to come forward with clear and convincing evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Regarding claim 3, the reagent portion of Takayama includes a plurality of reagent storing part (reservoirs 53-59) which includes a first and second storing portion (e.g., reads on chambers 56-59). The aforementioned first reagent storing part communicates the second reagent storing part via the channels 43, 44, 45 when the reagent cartridge 50, 60 and the testing cartridge 40 are attached (col. 7, lines 5+).

Similarly, as to claims 4-6, the Takayama reference is silent as to the process of retaining a first reagent cartridge at a lower temperature than a second reagent cartridge before being attached to the centrifuge. Takayama also is silent as to the process by which the testing cartridge is retained at a lower temperature than the reagent cartridge before attachment to the centrifuge and the volume of the first reagent cartridge being smaller than a volume of the second reagent cartridge is disclosed.

Again, these aforementioned limitations of claim 4-6 are considered by the Examiner product-by-process limitations that are not believed to impart distinctive structural characteristics to the final product since the claimed product appears to be the same or similar to that of the prior art, although produced by a different process. Although produced by a different process, the burden shifts to Applicant to come forward with clear and convincing evidence establishing an unobvious difference between the claimed product and the prior art product.

Please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., using sample containing nucleic aid and a capturing reagent for capturing the nucleic acid) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Regarding claim 7, Takayama teaches a plurality of reagent cartridges, the first reagent cartridge (50, 60) is disposed facing toward a first region (top) of the testing cartridge and a second reagent cartridge 70 is disposed facing toward a second region

(bottom) of the testing cartridge. Likewise, the second reagent cartridge (50, 60) is disposed facing toward a first region (top) of the testing cartridge and a first reagent cartridge 70 is disposed facing toward a second region (bottom) of the testing cartridge. Nothing in claims 7-8 structurally distinguish the first and second reagent cartridges from each other.

Terminal Disclaimer

10. The terminal disclaimer filed on December 26, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 11/493,751 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

11. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection as set forth above.

Conclusion

12. No claims allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

pkw

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797